

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Bryan et al. PATENT NO. 5,865,846

SERIAL NO.: GROUP ART UNIT:

FILED: February 2, 2001 EXAMINER:

FOR: HUMAN SPINAL DISC PROSTHESIS

ATTORNEY DOCKET NO.: 46739/252388

Assistant Commissioner for  
Patents  
Washington, D.C. 20231

DATE: February 2, 2001

## REISSUE DECLARATION

Sir:

The undersigned, Vincent Bryan and Alex Kunzler, hereby declare as follows:

1. We are the named inventors of U.S. Letters Patent No. 5,865,846, entitled "Human Spinal Disc Prosthesis," which was granted on February 2, 1999, and our respective residences and countries of citizenship are provided below.
2. We verily believe ourselves to be the original, first and joint inventors of the invention described and claimed in U.S. Patent No. 5,865,846.
3. We verily believe United States Letters Patent No. 5,865,846 to be partially inoperative or invalid by reason of our claiming less than we had a right to claim, and by reason

of errors therein.

4. The errors in the original Letters Patent were discovered as a result of recent discussions between in-house counsel and outside counsel during a review of assignee's patent portfolio by in-house counsel.

5. During those discussions, it was discovered that claims 1-9 of the patent contained limitations that were not necessary for the claims to be patentable over the art of record.

6. More particularly, during this review, it was discovered that claims 4, 8, and 9 recited steps that were not necessary for patentability over the art of record.

7. In claim 4, the steps of removing the vertebral disc from the spine, forming holes at predetermined locations, tapping the holes, and threadably implanting anchors into the holes were not required for the claim to be patentable over the art of record.

8. In claim 8, the step of mounting the intervertebral disc endoprosthesis by means of the original mounting holes, and the limitation that the outer surfaces of the endoprosthesis mate "precisely" were not required for the claim to be patentable over the art of record.

9. In claim 9, the step of thereafter constructing the intervertebral disc endoprosthesis was not required for the claim to be patentable over the art of record.

10. In addition, claims 4, 8, and 9 use language that could be construed as overly limiting "step plus function" language under 35 U.S.C. § 112, paragraph 6, and which language is unnecessary to render these claims patentable over the art of record.

11. In addition to claiming less than we had a right to claim, the claims contain errors that render them wholly or partially inoperative or invalid.

12. More particularly, claims 4, 8, and 9 each refer to a "vertebral disc," which does not exist, and should instead refer to an "intervertebral disc"

13. The aforementioned defects in the claims arose during the prosecution of the application that resulted in the original Letters Patent because of the applicants' and attorney's failure to appreciate the full scope of the invention. More specifically, it was believed that the limitations to the claims described above in paragraphs 7-10 were necessary to completely recite the method, and it was not appreciated that claims to a method reciting forming concave surfaces in the endplates of the vertebral bodies and inserting an endoprosthesis therebetween would be patentable. It was also not appreciated that claims to methods where the endoprosthesis was not mounted to the vertebral bodies by the original mounting holes would be patentable. Further, it was not appreciated that methods where the endoprosthesis was not constructed after receiving information about the patient's vertebral bodies would be patentable. The full implications of the use of "steps of" language, and the possibility that this language would be interpreted in accordance with 35 U.S.C. § 112, sixth paragraph, were not fully appreciated or understood by applicants or their attorney.

14. The errors in the claims were discovered during a recent review of the patent portfolio of the assignee, which resulted in a reassessment of the scope of the claims in the patent, and the realization that claims should have been sought that recited the novel and nonobvious features of the invention, and did not recite features that were unnecessary to patentability.

15. After becoming aware of the aforementioned errors, a detailed review of the prosecution history of the original application was undertaken to ascertain how the errors occurred, and the present application for reissue of United States Letters Patent 5,865,846 was promptly prepared. Amendments to claims 4, 8, and 9 were prepared in the form of the accompanying Preliminary Amendment to correct the above defects and errors, and to render the

claims more readable, and additional dependent claims 10-18 were added to provide more comprehensive claim coverage and to replace existing claims 5-7.

16. This application for Letters Patent addresses the aforementioned defects in the claims. These errors arose through inadvertence, and without any deceptive intention on our part.

17. We verily believe ourselves to be the first, original and joint inventors of the subject matter that is claimed in this application for reissue and for which reissue of the original Letters Patent on the invention entitled "Human Spinal Disc Endoprosthesis" is sought, and do not believe that the invention was ever known or used before our invention thereof was made.

18. We have reviewed and understand the contents of the specification, including the claims as presented in the accompanying application for reissue.

19. We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §§ 1.56(a).

20. We offer to surrender U.S. Letters Patent No. 5,865,846, conditioned upon the reissue of said Letters Patent.

21. We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's signature Vincent Bryan Date Feb 2 / 2001

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